

wherein R is a water-solubilizing group selected from (1) - $(\text{CH}_2)_n\text{X}$, where n is 1 to 5, X is either (I) $-\text{SO}_3\text{M}$ where M is hydrogen, an alkali metal, an alkaline earth metal or an ammonium (NH_4^+) cation, or (II) $(-\text{OCH}_2\text{CH}_2)_y\text{OH}$ where y is 2 to 5; and (2) - $\text{N}(\text{R}_7)_3^+\text{Z}^-$ where each R_7 is independently selected from alkyl of 1 to 4 carbon atoms, and Z is an acid anion;

R_1 and R_6 are taken together to represent an ethylene, trimethylene, or tetramethylene group which forms a partially saturated ring; and

R_2 , R_3 , and R_4 are independently selected from hydrogen, alkyl of 1 to 4 carbon atoms, and alkoxy of 1 to 4 carbon atoms;

(b) a porous spreading layer; and

(c) a buffer which maintains the pH of the element in a range of between about 6.5 to 8.5.

REMARKS

Claims 9-11 and 13-17 are pending. Applicants have hereinabove amended claim 9 to more clearly describe and distinctly claim the subject matter of the instant invention. Support for amending claim 9 to recite language concerning gelatin may be found in the specification at, inter alia, page 3,

lines 14-16. The remaining amendments to the claims introduce only minor format and grammatical changes. Accordingly, the amendments to the claims raise no issue of new matter.

In view of the amendments to the claims and the arguments put forth herein, applicants maintain that the Examiner's rejections have been overcome and respectfully request that they be withdrawn.

Rejections Under 35 U.S.C. 103

The Examiner rejected claims 9-11, 14 and 17 under 35 U.S.C. 103 as allegedly unpatentable over Arter or Hammond in view of either Matsumoto or DeCastro and further in view of Batz. The Examiner also rejected claims 13, 15 and 16 under 35 U.S.C. 103 as allegedly unpatentable over Arter or Hammond in view of either Matsumoto or DeCastro, further in view of Batz, and further in view of Kawaguchi.

In response to the Examiner's rejections, but without conceding the correctness thereof, applicants have amended the claims to more clearly describe the instant invention.

The invention, as now claimed, provides a dry analytical element for determining acetaminophen in an aqueous fluid. The analytical element uses an arylacylamidase enzyme reaction and employs, in relevant part, a ferricyanide oxidizing agent, a non-hardening gelatin component, and a buffered pH of from about 6.5 to 8.5.

This analytical element surprisingly overcomes problems known in the art in at least two important ways. First, the ferricyanide oxidizing agent, as used in this invention, would

have been expected to fail as a suitably rapid oxidizing agent within the neutral pH range used here. This expectation of failure is based on the relative weakness of Fe^{+++} as an oxidizing agent compared to other metal oxidizing agents (see, e.g., Table A, page 19 of the specification). Unexpectedly, however, the ferricyanide used in this element permits the very rapid generation of a detectable colored signal -- in only 57 seconds (see page 4, line 29 of the specification).

Second, the ferricyanide, as used in this invention, would have been expected to *chemically* attack the gelatin matrix also present in the element. This attack would have resulted in gelatin hardening due to chemical crosslinking, which in turn would have prevented the element from functioning properly (see, e.g., page 3, lines 14-16 of the specification). Surprisingly, however, the ferricyanide does not behave this way in the claimed analytical element. Rather, this analytical element possesses a *non-hardening* gelatin component as one of its *unexpected* features.

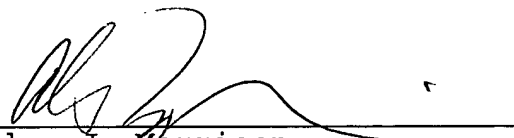
Applicants maintain that each of these two unexpected advantages would, *by itself*, render the claimed analytical element non-obvious over the cited combinations of references. At best, these combinations merely describe certain components of the claimed analytical element. Their combined teachings fail to provide an expectation of success, or even an impetus to try, regarding the instant invention.

For the reasons put forth above, the analytical element as now claimed would not have been obvious under 35 U.S.C. 103 over either of the stated combinations of references for the reasons stated.

For the sake of clarity, applicants traverse, in particular, the Examiner's numerous references in the May 27 Office Action to an oxidative "enzyme" allegedly present in the instant analytical element. The element as claimed has only the ferricyanide oxidative agent. Applicants also traverse the Examiner's position that in their response to the rejections under 35 U.S.C. 103 in the April 25, 1997 Amendment, applicants failed to consider the cited references in combination. In their Amendment, applicants made it very clear that they had considered the references in combination, and not just individually (see, e.g., page 6, line 31 and page 7, line 32 of the Amendment).

In view of the amendments and remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

Respectfully submitted,


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